VASCULAR INSTRUMENTS
KOVEN®
TECHNOLOGY INCORPORATED

JUL 2 8 2008

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the **Valvulotome by Koven**.

1. **Company making the submission:**

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Telephone:	314-542-2101 Voice 314-542-6020 Fax
Contact:	Heather Bell
E-mail:	hbell@koven.com
Submission Contact:	J. Harvey Knauss, Delphi Consulting Group
Address:	11874 South Evelyn Circle Houston, Texas 77071-3404
Telephone:	713-723-4080 Voice 832-615-3550 Fax
E-mail:	Harvey@delphiconsulting.com

2. **Device Name:**

Trade/Proprietary Name:	Valvulotome by Koven
Common/Usual Name:	Valvulotome - External Vein Stripper
Classification Name:	External Vein Stripper
Regulation Number:	870.4885
Product Code:	MGZ

3. **Predicate Devices:**

The **Valvulotome by Koven** is substantially equivalent to other Valvulotome devices in the market such as the Lemaitre Valvulotome II, K946352, manufactured by Vascutech, Inc., North Andover, MA 01854.

4. Indications for Use Statement

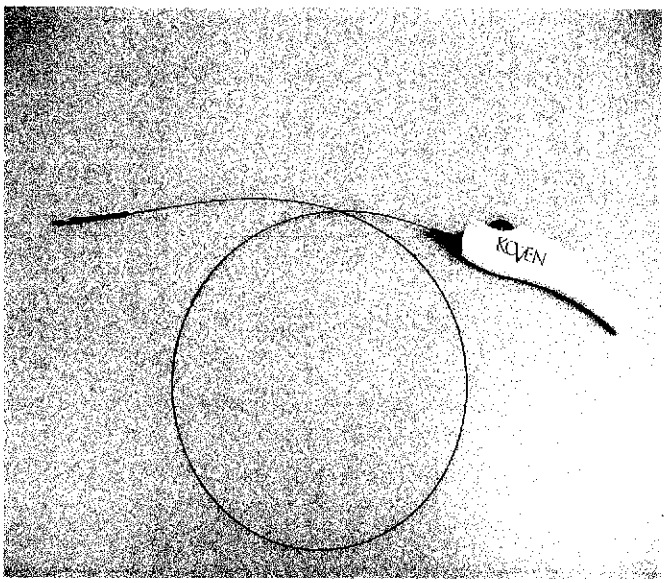
The **Valvulotome by Koven** Valvulotome is used for the treatment of vascular disorders and more particularly for excising or disrupting venous valves when performing in-situ vascular procedures, such as lower extremity arterial bypass surgery.

5. Description of Device:

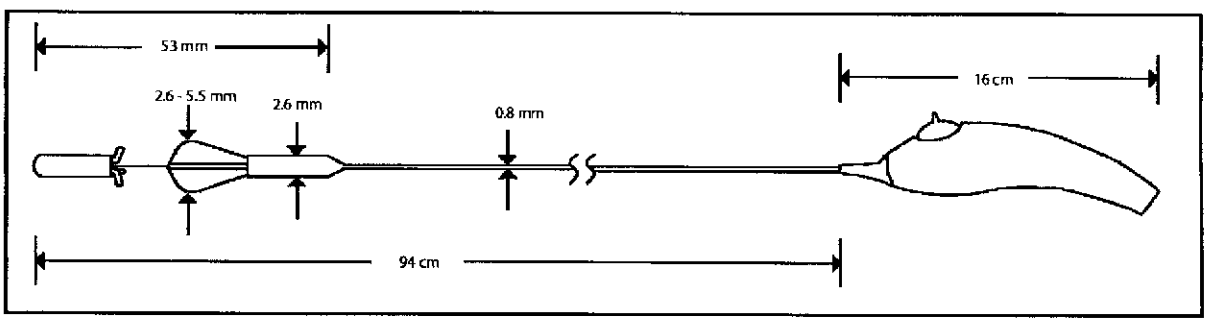
The **Valvulotome by Koven** is a medical device that has a deployable assembly with multiple deployable cutting blades and guide fins which permit continual centralizing, and alignment of the cutting blades within the lumen of the vein as the valves are being cut. The device includes a handle operatively associated with this deployable assembly through a catheter operated by the handle in a one-handed operation for deploying the guide fins and cutting blades of the deployable assembly having respective outer diameters at each deployment position.

The **Valvulotome by Koven** consists of three main parts; the handle, the catheter and the cutter head as shown.

1. The handle is fabricated through injection molded plastics that are assembled using adhesive and mechanical fasteners. The material used is a Medical Grade Acrylic and a Medical Grade Thermoplastic Elastomer.
2. The catheter is fabricated through an extrusion process and an adhesive bond. The materials used are a Medical Grade Natural Polyetheretherketone and medical grade adhesive.



3. The cutter head is fabricated through machining, etching, drawing and stamping and assembled using a welding process. All materials in the cutter head are made from 300 series Stainless Steel.



The **Valvulotome by Koven** are packaged using a Medical Grade Polyethylene Terephthalate Glycol tray and lid. The tray with lid shall be placed inside a sealed Tyvek pouch, which will be placed, along with an "Instructions for Use" booklet, inside a shelf carton with two protective form pads. The device label will appear on both the pouch and the shelf carton. The device and its packaging will be sterilized using irradiation sterilization method.

6. Summary of the technological characteristics of the device compared to predicate device:

Differences in technology – None.

The basic method of construction and materials is very similar. The methods of operation and indications for use are the same for each device.

7. Testing:

Testing of the **Valvulotome by Koven** included laboratory bond strength testing of all joined elements, bench testing for the determination of adequacy and safety of the device for the disruption of valves in blood vessels of the leg.

The **Valvulotome by Koven** successfully completed all testing with positive end points achieved.

8. Rx or OTC:

The **Valvulotome by Koven** is a Rx prescription device per 21 CFR Subpart D. The device is labeled for clinical settings only. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

9. Conclusions:

Based upon the testing and comparison to the predicts device the **Valvulotome by Koven** has the same intended use, with similar technological characteristics. Koven Technology, Inc., therefore posits that its device is substantiality equivalent to predicate devices.

Koven Technology, Inc.

Heather Bell
President Koven Technology, Inc.

Date: 7-17-08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2008

Koven Technology
c/o Mr. Harvey Knauss
Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K080178
Trade/Device Name: Valvulotome by Koven
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II
Product Code: MGZ
Dated: July 1, 2008
Received: July 8, 2008

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number **K080178**
Device Name: **Valvulotome by Koven**

The **Valvulotome by Koven** is used for the treatment of vascular disorders and more particularly for excising or disrupting venous valves when performing in-situ vascular procedures, such as lower extremity arterial bypass surgery.

Prescription Use **Yes** (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Mitchell
(Division Sign-Off)
Division of Cardiovascular

510(k) Number K080178